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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/807,732

03/24/2004

Young-Min Kim

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ANDERSON, KILL & OLICK, P.C.
1251 AVENUE OF THE AMERICAS
NEW YORK,, NY 10020-1182

EXAMINER

ALLEN, MARIANNE P

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/807,732	Applicant(s) KIM ET AL.	
	Examiner Marianne P. Allen	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2007 and 14 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/6/07, 4/10/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 21 and 25-53 have been cancelled. Claims 1-20 and 22-24 are under consideration. A complete listing of the claims was filed on 6/14/07.

Applicant's arguments filed 3/21/07 have been fully considered but they are not persuasive.

The rejection of claims 1-6 and 9-24 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-22 of copending Application No. 10/659,195 is withdrawn in view of the abandonment of 10/659,195.

The provisional rejection of claims 7-8 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/659,195 is withdrawn in view of the abandonment of 10/659,195.

The rejection of claims 18-19 and 23-24 under 35 U.S.C. 103(a) as being unpatentable over Mohamed et al. (US 2006/0153839) in view of Rosen et al. (US 2004/0115165) is withdrawn in view of the amendments to the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 and 22-24 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 10/535,232. Although the conflicting claims are not identical, they are not patentably distinct from each other because although worded differently, the conflicting claims embrace overlapping embodiments of protein conjugates.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments are not persuasive. The term "immunoglobulin" in the claims are not limited to whole immunoglobulins. Page 7 makes clear that this term embraces fragments and mutated forms. The Fc fragment of the '232 application would be embraced by these claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1 and 18 have been amended such that the physiologically active polypeptide excludes an immunoglobulin and a fragment thereof. No basis has been pointed to and none is apparent for the introduction of this negative limitation. At least for example, unamended claim 15 makes clear that an antibody (or immunoglobulin) is a desirable physiologically active polypeptide.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9 and 11-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Heavner (US 2003/0211078).

This rejection is maintained for reasons of record.

Heavner discloses bifunctional molecules where PEG is bound at one end to a physiologically active polypeptide and at the other end to an immunoglobulin. The molecules have improved half life. The PEG has reactive groups at either end. Reactive groups specifically disclosed include maleimide and aldehyde. The PEG is linked to the amino terminal residue lysine or cysteine of the immunoglobulin or physiologically active polypeptide. The immunoglobulin can be an IgG, particularly IgG1. The proteins can be made recombinantly

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which would alter the nature of glycosylation depending upon the host cell in which it is produced. Physiologically active polypeptides include erythropoietin (EPO), cytokines such as tumor necrosis factor (TNF), blood proteins such as Factor VII. See abstract, figures, claims, Tables 1-4, Examples, paragraphs [0042, 0068-0075, 0086, 0091].

The molecules of Heavner et al. meet the structural and functional limitations of the claims. Contrary to applicant's arguments, the claims do not require a whole immunoglobulin. The definition on page 7 includes fragments. Contrary to applicant's arguments, the claims do not require any particular amount or degree of increased half-life. The use of the term "comprising" permits the inclusion of additional components. The conjugate is not limited to only those components recited in the claims.

Claims 1-2, 9-10, 18-20, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Mohamed et al. (US 2006/0153839).

This rejection is maintained for reasons of record.

Mohamed et al. claims priority to and is entitled to benefit of 60/411,731. The effective filing date of Mohamed et al. is 9/16/02 and as such is valid prior art against the instant application.

Mohamed et al. discloses bifunctional molecules where PEG is bound at one end to a physiologically active polypeptide and at the other end to an immunoglobulin. Mohamed et al. discloses conjugating to PEG via succinimide derivatives. Example 6.2 conjugates PEG to a first antibody at a molar ratio of 3:1 followed by separation via chromatography before further conjugating to the second antibody. See at least abstract, claims, and paragraphs [0112-0117].

The molecules of Mohamed et al. meet the structural limitations of the claims. Contrary to applicant's arguments, the claims do not require a whole immunoglobulin. The definition on page 7 includes fragments. PEG would have been well known at the time of the invention to increase in vivo half life (as is clear from the prior art of record) and as such, the bifunctional molecules of Mohamed et al. would inherently possess this feature absent evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa